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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,605	10/11/2001	Grant McFadden	50082/015002	3282

21559 7590 12/20/2002

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,605

Applicant(s)

MCFADDEN ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group 1, claim(s) 1, 3, 4, 9, 10, 42 and 43 drawn to a polypeptide of a *Yatapoxvirus* and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 1, a Tanapox virus protein sequence, classified in class 530, subclass 350.
- Group 2, claim(s) 1, 2, 4, 9, 10, 42 and 43 drawn to a polypeptide of a *Yatapoxvirus* and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 2, a Yaba Monkey Tumor Virus protein sequence, classified in class 530, subclass 350.
- Group 3, claim(s) 1, 3, 9, 10, 42 and 43 drawn to a polypeptide of a *Yatapoxvirus* and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 4, a Tanapox virus protein sequence, classified in class 530, subclass 350.
- Group 4, claim(s) 1, 9, 10, 42 and 43 drawn to a polypeptide of a *Yatapoxvirus* and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 6, a Yaba-like disease virus protein sequence, classified in class 530, subclass 350.
- Group 5, claim(s) 1, 42 and 54 drawn to a polypeptide of a *Yatapoxvirus* and a pharmaceutical composition comprising the polypeptide of SEQ ID NO: 8, a Swinepox virus protein sequence, classified in class 530, subclass 350.
- Group 6, claim(s) 1, 4-8 drawn to a polypeptide of a *Yatapoxvirus*, classified in class 530, subclass 350.
- Group 7, claim(s) 11-14, 16-26, 32, 33 and 47, drawn to the nucleic acid encoding a *Yatapoxvirus* protein, the nucleotide sequence comprises SEQ ID NO: 3, a Yaba Monkey Tumor Virus sequence, classified in class 536, subclass 23.72.
- Group 8, claim(s) 11-13, 15-26, 32, 33 and 47, drawn to the nucleic acid encoding a *Yatapoxvirus* protein, the nucleotide sequence comprises SEQ ID NO: 5 a Tanapox virus sequence, classified in class 536, subclass 23.72.
- Group 9, claim(s) 11-13, 15-17, 19-26, 32, 33 and 47, drawn to the nucleic acid encoding a *Yatapoxvirus* protein, the sequence comprises SEQ ID NO: 1, a Tanapox virus sequence, classified in class 536, subclass 23.72.
- Group 10, claim(s) 11-13, 16-26, 32, 33 and 47, drawn to the nucleic acid encoding a *Yatapoxvirus* protein, the nucleotide sequence comprises SEQ ID NO: 7, a Yaba-like disease virus sequence, classified in class 536, subclass 23.72.

- Group 11, claim(s) 27-29, drawn to a transgenic animal comprising a *Yatapoxvirus* gene, classified in class 800, subclass 14.
- Group 12, claim(s) 30, 31 and 48, drawn to an antibody to a *Yatapoxvirus* protein.
Selection of one of the following species SEQ ID NO: 1, a Tanapox virus protein sequence, classified in class 530, subclass 389.1.
- Group 13, claim(s) 30, 31 and 48, drawn to an antibody to a *Yatapoxvirus* protein.
Selection of one of the following species SEQ ID NO: 2, a Yaba Monkey Tumor Virus protein sequence, classified in class 530, subclass 389.1.
- Group 14, claim(s) 30, 31 and 48, drawn to an antibody to a *Yatapoxvirus* protein.
Selection of one of the following species SEQ ID NO: 4, a Tanapox virus protein sequence, classified in class 530, subclass 389.1.
- Group 15, claim(s) 30, 31 and 48, drawn to an antibody to a *Yatapoxvirus* protein.
Selection of one of the following species SEQ ID NO: 6, a Yaba-like disease virus protein sequence, classified in class 530, subclass 389.1.
- Group 16, claim(s) 34, drawn to a method of detecting a polypeptide of a *Yatapoxvirus*, classified in class 435, subclass 7.1.
- Group 17, claim(s) 35, drawn to a method of detecting a gene of a *Yatapoxvirus* comprising SEQ ID NO: 3, classified in class 435, subclass 6.
- Group 18, claim(s) 35, drawn to a method of detecting a gene of a *Yatapoxvirus* comprising species SEQ ID NO: 5, classified in class 435, subclass 6.
- Group 19, claim(s) 35, drawn to a method of detecting a gene of a *Yatapoxvirus* comprising SEQ ID NO: 7, classified in class 435, subclass 6.
- Group 20, claim(s) 36, drawn to a method of identifying an immunomodulator gene of a *Yatapoxvirus*, classified in class 900, subclass 34.
- Group 21, claim(s) 37 and 43, drawn to identifying a test compound that modulates the expression of a *Yatapoxvirus* gene comprising a substantially identical sequence to SEQ ID NO: 1, classified in class 435, subclass 4.
- Group 22, claim(s) 37 and 43, drawn to identifying a test compound that modulates the expression of a *Yatapoxvirus* gene comprising a substantially identical sequence to SEQ ID NO: 2, classified in class 435, subclass 4.

- Group 23, claim(s) 37 and 43, drawn to identifying a test compound that modulates the expression of a *Yatapoxvirus* gene comprising a substantially identical sequence to SEQ ID NO: 4, classified in class 435, subclass 4.
- Group 24, claim(s) 37 and 43, drawn to identifying a test compound that modulates the expression of a *Yatapoxvirus* gene comprising a substantially identical sequence to SEQ ID NO: 6, classified in class 435, subclass 4.
- Group 25, claim(s) 49 and 55, drawn to identifying a test compound that modulates the expression of a *Yatapoxvirus* gene comprising a substantially identical sequence to SEQ ID NO: 8., classified in class 435, subclass 4.
- Group 26, claim(s) 38 and 43, drawn to a method of targeting protein for secretion from a cell, the protein comprising a sequence substantially identical to SEQ ID NO: 1, classified in class 435, subclass 69.8.
- Group 27, claim(s) 38 and 43, drawn to a method of targeting protein for secretion from a cell, the protein comprising a sequence substantially identical to SEQ ID NO: 2, classified in class 435, subclass 69.8.
- Group 28, claim(s) 38 and 43, drawn to a method of targeting protein for secretion from a cell, the protein comprising a sequence substantially identical to SEQ ID NO: 4, classified in class 435, subclass 69.8.
- Group 29, claim(s) 38 and 43, drawn to a method of targeting protein for secretion from a cell, the protein comprising a sequence substantially identical to SEQ ID NO: 6, classified in class 435, subclass 69.8.
- Group 30, claim(s) 50 and 55, drawn to a method of targeting protein for secretion from a cell, the protein comprising a sequence substantially identical to SEQ ID NO: 8, classified in class 435, subclass 69.8.
- Group 31, claim(s) 39-41, 43 and 44-46, drawn to a method of immunomodulating a response in an animal, the protein comprising a sequence substantially identical to SEQ ID NO: 1, classified in class 424, subclass 9.2.
- Group 32, claim(s) 39-41, 43 and 44-46, drawn to a method of immunomodulating a response in an animal, the protein comprising a sequence substantially identical to SEQ ID NO: 2, classified in class 424, subclass 9.2.
- Group 33, claim(s) 39-41, 43 and 44-46, drawn to a method of immunomodulating a response in an animal, the protein comprising a sequence substantially identical to SEQ ID NO: 4, classified in class 424, subclass 9.2.

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Group 34, claim(s) 39-41, 43 and 44-46, drawn to a method of immunomodulating a response in an animal, the protein comprising a sequence substantially identical to SEQ ID NO: 6, classified in class 424, subclass 9.2.

Group 35, claim(s) 51-53 and 55-58, drawn to a method of immunomodulating a response in an animal, the protein comprising a sequence substantially identical to SEQ ID NO: 8, classified in class 424, subclass 9.2.

For each invention of groups 6 above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of groups I-III, election is further required for one of inventions (A)-(D).

- (A). chemokine binding protein.
- (B). cytokine binding protein.
- (C). an immunomodulator.
- (D). an anti-inflammatory polypeptide.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides. Therefore, where structural identity is required, the different sequences have different effects.

Inventions 7-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides encoding them. Therefore, where

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structural identity is required, such as for hybridization or expression or activity, the different sequences have different effects.

Inventions 12-15 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different antibodies recognizing different polypeptides. Therefore, where structural identity is required, such as in an antibody protein interaction the different sequences have different effects.

Group 11 is drawn to a transgenic animal, which is a composition and differs from method claims. Groups 16-35 are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Group 16 is drawn to a method of detecting polypeptides with an antibody. Groups 17-19 are drawn to a method of detecting nucleic acid sequences using probes and primers. Group 20 is drawn to a method of identifying immunomodulator. Groups 21-25 are drawn to a method identifying test compounds that modulate the expression of genes. Groups 26-30 are drawn to a methods of targeting proteins for secretion. Groups 31-35 are drawn to a method of modulating an immune response in an animal. Though there may be overlap between these methods in question for groups 16-35, each utilizes different materials and therefore the outcome is expected to be different.

Inventions 12-15 and 16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used for processes of purifying the protein via affinity chromatography.

Inventions 7-10 and 17-19 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polynucleotides can be used for the production of the protein they encode.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D. 12/19/02